UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE AXSOME THERAPEUTICS, INC. SECURITIES LITIGATION	22 Civ. 3925 (LGS)
	OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Lead Plaintiffs Thomas Giblin, Paul Berger and Paul Sutherland ("Plaintiffs"), individually and on behalf of all other persons similarly situated, bring this putative class action against Herriot Tabuteau, Nick Pizzie, Mark Jacobson, Cedric O'Gorman and Kevin Laliberte (the "Individual Defendants") and Axsome Therapeutics, Inc. ("Axsome" or the "Company"). The Second Amended Complaint ("SAC") alleges securities fraud in violation of § 10(b) and § 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. Defendants move to dismiss the SAC for failure to state a claim. For the following reasons, the motion is denied in part and granted in part.

I. BACKGROUND

The following facts are taken from the SAC, documents referenced in the SAC or are matters of which judicial notice may be taken, including public filings. *See Dixon v. von Blanckensee*, 994 F.3d 95, 101-02 (2d Cir. 2021); *United States v. Am. Soc'y of Composers, Authors & Publishers*, 627 F.3d 64, 69 n.2 (2d Cir. 2010) (public filings).

A. The Parties

Defendant Axsome is a publicly traded biopharmaceutical company that develops therapies for central nervous system ("CNS") disorders. Plaintiffs purchased Axsome securities

between May 10, 2021, and April 22, 2022 (the "Class Period"). Defendants Tabuteau, Pizzie, Jacobson, O'Gorman and Laliberte were Axsome executive officers during part or all of the Class Period. Defendant Tabuteau has served as Axsome's Chief Executive Officer ("CEO") and Chairman of the Board of Directors since founding the Company in 2012. Defendant Jacobson has been Axsome's Chief Operating Officer ("COO") since March 2020. Defendant Laliberte was Axsome's Executive Vice President of Product Strategy from January 2021 to December 2021. Defendant O'Gorman was Axsome's Senior Vice President of Clinical Development and Medical Affairs from September 2017 to September 2021. Defendant Pizzie has been Axsome's Chief Financial Officer ("CFO") since May 2018.

B. The Alleged Fraud and Ultimate Disclosure

The SAC alleges securities fraud during Axsome's development of AXS-07, one of Axsome's core drug products from its CNS portfolio. The SAC alleges material omissions and misstatements made during the Class Period related to Defendants' failure to disclose that Axsome encountered manufacturing equipment problems and resulting supply delays in the development of AXS-07. The SAC alleges that because of this omission, statements about the timeline and prospect of U.S. Food and Drug Administration (the "FDA") approval for AXS-07 were false or misleading.

The SAC alleges that Defendants' misstatements began on May 10, 2021, the first day of the Class Period. That day, the Company filed its Q1 2021 10-Q in which it incorporated its previously filed 2020 10-K, restating its belief that "existing suppliers of our product candidate active pharmaceutical ingredients and finished products will be capable of providing sufficient qualities of each to meet our clinical trial supply needs."

After Axsome filed AXS-07's new drug application ("NDA") with the FDA in June 2021, Defendants continued to state the positive prospects for FDA approval and lack of manufacturing concerns regarding AXS-07 through press releases, investor conference calls and public filings. For example, on an August 9, 2021, earnings conference call, Defendant Jacobson responded to a question about manufacturing problems that had delayed AXS-05, another one of Defendants' core drugs:

> So for the manufacturing process for AXS-07, that actually is a bit more complicated and there are two facilities that we utilized for the manufacturer of the drug product. The drug -- the API's [application programming interface] are also available under open DMF [drug master file] too in the U.S. And of the two facilities that we used for drug product manufacturing, one of them is the same that we used for AXS-05.

Also, on August 9, 2021, Axsome publicly filed its Q2 2021 results and again, by incorporation, reiterated its belief that its suppliers would be capable of providing sufficient materials to meet their clinical trial needs. The Company reiterated by incorporation the same belief in public filings on November 8, 2021, and March 1, 2022. On March 1, 2022, Axsome issued a press release quoting Defendant Tabuteau's statement that:

> 2021 was a year of continued progress which has put us in a position to potentially launch two new investigational medicines for patients living with depression and migraine. [Specifically,] the April 30 PDUFA [Prescription Drug User Fee Act] date for our NDA for AXS-07 in the acute treatment of migraine is approaching.

Some of the SAC's allegations are based on information from a confidential witness ("CW 1"), a former Senior Clinical Trial Manager at Axsome during the Class Period. In early 2021, CW 1 was tasked with managing a new study, slated to begin at the end of April 2021, to provide additional data for AXS-07 to support the drug's marketing. Axsome delayed this study first until August 2021, then November 2021, and then early 2022 because of a lack of supply of

AXS-07 caused by issues with equipment used by one of Axsome's drug ingredient vendors. Those manufacturing problems impacted Axsome's entire supply of AXS-07.

According to CW 1, the manufacturing problems persisted from at least April 2021 through February 2022 and had not been resolved when CW 1 left the Company. In the summer of 2021, Axsome conducted an internal audit of its chemistry, manufacturing and controls ("CMC") and manufacturing facilities, which raised equipment problems. CMC requirements ensure that the manufacturing process produces a safe and effective drug even when production is scaled up for commercial sale following FDA approval. The Company's equipment problems were discussed at an internal meeting that CW 1 attended with Defendant Laliberte. In early 2022, CW 1 was told that the manufacturer was still having equipment problems.

Axsome publicly disclosed AXS-07's manufacturing problems on Monday, April 25, 2022 -- shortly after Friday, April 22, 2022, the last day of the Class Period. Axsome announced that the FDA had informed the Company that CMC issues were "unresolved," and that the Company expected additional FDA feedback on or around April 30, 2022. In response to this news, Axsome's stock price dropped approximately 22% that day. On May 2, 2022, Axsome announced that it had received the FDA Complete Response Letter ("CRL"), which identified the need for additional CMC data pertaining to AXS-07 and the manufacturing process.

C. Procedural History

This putative class action was filed on May 13, 2022. Former Plaintiffs Evy Gru and Santoshanad Thakkar were appointed co-lead Plaintiffs. Plaintiff Thakkar then withdrew from the litigation. Defendants' motion to dismiss the then-operative complaint was granted because Gru had sold all of his Axsome securities before any corrective disclosure. *Gru v. Axsome Therapeutics, Inc.*, No. 22 Civ. 3925, 2023 WL 6214581, at *4 (S.D.N.Y. Sept. 25, 2023).

Plaintiff timely sought leave to replead with new plaintiffs. After the appointment of Giblin, Berger and Sutherland as new Lead Plaintiffs, their request to file the SAC was granted. On March 11, 2024, Defendants (in two separate groups) filed the instant motions to dismiss.

II. STANDARD

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *accord Kaplan v. Lebanese Canadian Bank, SAL*, 999 F.3d 842, 854 (2d Cir. 2021). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must "nudge[]" claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570; *accord Bensch v. Est. of Umar*, 2 F.4th 70, 80 (2d Cir. 2021). To survive dismissal, a complaint's "factual allegations must be enough to raise a right to relief above the speculative level." *Melendez v. Sirius XM Radio, Inc.*, 50 F.4th 294, 306 (2d Cir. 2022).[1] On a Rule 12(b)(6) motion, "all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff's favor." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016); *accord Francis v. Kings Park Manor, Inc.*, 992 F.3d 67, 72 (2d Cir. 2021). However, a court does not consider "conclusory allegations or legal conclusions couched as factual allegations." *Dixon*, 994 F.3d at 101.

"A complaint alleging securities fraud must also satisfy heightened pleading requirements set forth in Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA)." *Set Cap. LLC v. Credit Suisse Grp. AG*, 996 F.3d 64, 75 (2d Cir. 2021).

[1] Unless otherwise indicated, in quoting cases, all internal quotation marks, alterations, emphases, footnotes and citations are omitted.

"Rule 9(b) requires litigants to state with particularity the circumstances constituting fraud." *Id.* "To do so, a plaintiff must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* "The PSLRA, in turn, requires a plaintiff alleging securities fraud to (1) specify each misleading statement, (2) set forth the facts on which a belief that a statement is misleading was formed, and (3) state with particularity facts giving rise to a 'strong inference' that the defendant acted with scienter -- the required state of mind." *Id.* (quoting 15 U.S.C. § 78u-4(b)(2)(A)).

III. DISCUSSION

The SAC asserts a claim of securities fraud under § 10(b) of the Exchange Act and its implementing rule, Rule 10b-5. That rule makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). The SAC also asserts a claim of control person liability under § 20(a) of the Exchange Act. Defendants Axsome, Tabuteau and Jacobson's motion to dismiss both claims is denied. Defendants Laliberte, O'Gorman and Pizzie's motion to dismiss is granted.

A. Confidential Witness

The SAC relies principally on information from CW 1. "A complaint may rely on information from confidential witnesses if they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford*, 794 F.3d 297, 305 (2d Cir. 2015); *accord In re DraftKings Inc. Sec. Litig.*, 650 F. Supp. 3d 120, 154 (S.D.N.Y. 2023). Thus, when sufficiently described, "[a]s a general matter, courts consider and take as true

the statements of confidential witnesses at [the pleading] stage." *In re AppHarvest Sec. Litig.*, 684 F. Supp. 3d 201, 261 (S.D.N.Y. 2023).

The SAC describes CW 1 with sufficient particularity to support the probability that CW 1 would possess the information alleged. The SAC describes CW 1 as a "Senior Clinical Trial Manager" from July 2019 to February 2022 who "was tasked with managing a new study" related to AXS-07 that was delayed due to a lack of AXS-07 supply. The SAC further describes CW 1 as having reported to the Executive Director of Clinical Research, who reported to Defendant Tabuteau; the Director of Clinical Operations and the Senior Director of Clinical Operations; and being informed of AXS-07's manufacturing and supply issues by Axsome's Senior Director of AXS-07's Supply Chain, Fang Liu, who reported to Defendants Jacobson and Laliberte.

These allegations "suggest [CW 1] would have knowledge" about the manufacturing and supply of AXS-07 and who in the Company was similarly informed. *In re GigaCloud Tech. Inc. Sec. Litig.*, No. 23 Civ. 10645, 2025 WL 307378, at *7 (S.D.N.Y. Jan. 27, 2025) (finding confidential witness sufficiently described where complaint described their position and responsibilities). For purposes of this motion to dismiss, CW 1's allegations are accepted as true. Defendants' counterarguments regarding CW 1's allegations are addressed below in the discussion of scienter.

B. Section 10(b) Violation

The SAC sufficiently alleges a claim of federal securities fraud. To state a claim of securities fraud, "a plaintiff must plead: (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance on the misrepresentation or omission, (5) economic loss, and (6) loss

causation." *Noto v. 22nd Century Grp., Inc.*, 35 F.4th 95, 102 (2d Cir. 2022). "The first two elements must be pled with heightened specificity pursuant to the Private Securities Litigation Reform Act of 1995 and Federal Rule of Civil Procedure 9(b)." *Id.* at 102-03.

Principally at issue on this motion is whether the SAC sufficiently pleads three elements of securities fraud -- a material misrepresentation or omission, scienter and loss causation.

1. Material Misrepresentations or Omissions

The SAC alleges two categories of material misstatements -- (1) Defendants' statements that the manufacturing facility and suppliers for AXS-07 were not experiencing problems and (2) Defendants' statements about AXS-07's NDA. The SAC sufficiently pleads material misrepresentations or omissions concerning the former category by Defendant Jacobson, and both categories by Defendant Tabuteau. The SAC fails to allege actionable misstatements or omissions by Defendant Laliberte. As Defendants Pizzie and O'Gorman are dismissed because of lack of scienter as discussed below, their alleged misstatements are not addressed here.

A material misstatement or omission requires either (1) "an actual *statement*" that is "untrue outright," or (2) a half-truth, i.e., a "representation[] that state[s] the truth only so far as it goes, while omitting critical qualifying information." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239-40 (2d Cir. 2016). "The statement must . . . be misleading, evaluated not only by literal truth, but by context and manner of presentation." *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019). "[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (quoting Rule 10b-5, 17 C.F.R. § 240.10b-5); *accord Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*,

28 F.4th 343, 353 (2d Cir. 2022). "[O]nce a company speaks on an issue or topic, there is a duty to tell the whole truth, even where there is no existing independent duty to disclose information on the issue or topic." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d at 258.

a. Statements about Manufacturing Capability

The SAC adequately pleads that Defendants Tabuteau and Jacobson made material misstatements or omissions about the sufficiency of the Company's supply of AXS-07 and its manufacturing capabilities. The SAC alleges that the challenged manufacturing statements were false and misleading because they omitted the fact that the Company was experiencing manufacturing issues due to a supplier's equipment problems when the statements were made.

The SAC sufficiently pleads with particularity that Defendants' statements and omissions regarding its AXS-07 manufacturing capabilities were misleading. For example, in 2021 and 2022 public filings signed by Defendant Tabuteau, Axsome stated that they "believe[d] [their] existing suppliers" of AXS-07 would "be capable of providing sufficient quantities . . . to meet our clinical trial supply needs." On March 1, 2022, Axsome issued a press release by Defendant Jacobson, in which Defendant Tabuteau stated that "2021 was a year of continued progress which has put [the Company] in a position to potentially launch" AXS-07. These and similar statements about AXS-07 were misleading because they created an impression that the Company was not facing supply issues, when, in reality, the SAC alleges that Axsome was unable to produce sufficient AXS-07 for at least a year. The SAC's allegations regarding these misstatements are supported by CW 1's description of Axsome's vendor delays that extended beyond CW 1's marketing study and "delayed Axesome's entire supply of AXS-07." In short, the SAC as a whole alleges that, at least between April 2021 and February 2022, Axsome's supply of AXS-07 was inadequate due to a vendor's manufacturing issues. Defendants Tabutea

and Jacobson's manufacturing statements were material to investors because persistent manufacturing and supply problems could materially increase the likelihood of a delay in FDA approval. These allegations are sufficient to plead that Axsome's statements regarding or implying its AXS-07 manufacturing capabilities were misleading.

b. Statements About the NDA

The SAC adequately pleads that Defendant Tabuteau made material misstatements and omissions about Axsome's planned NDA submission for AXS-07. For example, Tabuteau signed Axsome's March 2022 public filings that stated that "in connection with the [CMC] data necessary for our NDA filing and approval, we will need to conduct stability studies and provide stability data to establish appropriate retest or expiration dating period."

The SAC alleges that such statements were misleading because they omitted the fact that, at the same time, Axsome could not obtain sufficient AXS-07 to conduct the necessary stability studies for almost a year, which would result in an inadequate NDA filing, which in turn would "almost certainly result[] in the FDA delaying or rejecting approval of AXS-07." Defendants allegedly acknowledged, in statements made after the Class Period, that testing batches of AXS-07 required stability testing over the span of a year that "cannot be sped up." The statements regarding the necessity of conducting such testing to obtain FDA approval were misleading because they implied that Axsome actually was conducting, or at least was able to conduct, stability testing.

c. Individual Defendant Laliberte

The SAC fails to allege material misstatements or omissions by Defendant Laliberte. The only alleged misstatements that the SAC specifically attributes to Laliberte were made during a November 2021 earnings call, in which he reported that the FDA had notified Axsome that its

inspection of the manufacturing site for AXS-07 may be delayed due to COVID, and he explained differences between AXS-07 and AXS-05, the latter of which had experienced regulatory difficulties arising from "analytical methods in the CMC." However, the SAC does not sufficiently allege that those statements were false or misleading. While Plaintiffs argue that the statements "promoted AXS-07's prospects for FDA approval" and "conceal[ed Axsome's] manufacturing problems," that characterization does not square with the statements' contexts, which instead show that the alleged misstatements were accurate statements of fact and did not imply anything false about the Company's supply of AXS-07 or the quality of its planned NDA. Defendant Laliberte's statements were not misleading "in light of the circumstances under which they were made." *Matrixx Initiatives, Inc.*, 563 U.S. at 44.

d. Defendants' Counterarguments

Defendants argue that their statements regarding Axsome's AXS-07 manufacturing capabilities and the NDA submission are inactionable because they were (1) forward-looking statements, (2) statements of opinion, (3) accurate statements of fact, (4) not so incomplete as to mislead, (5) mere puffery, (6) accompanied by sufficient risk warnings and (7) that, regardless, Defendants did not have a duty to disclose the manufacturing issues with AXS-07. None of those arguments are convincing.

Forward-looking statements. First, Defendants argue that some of the aforementioned misstatements are inactionable because they are forward-looking statements accompanied by sufficient risk warnings and protected by the PSLRA's Safe Harbor provision. "Under that provision a defendant is not liable if (1) the forward-looking statement is identified and accompanied by meaningful cautionary language, (2) the forward-looking statement is immaterial, or (3) the plaintiff fails to prove that the forward-looking statement was made with

actual knowledge that it was false or misleading." *In re Vivendi, S.A. Secs. Litig.*, 838 F.3d at 245. "Courts in this circuit have consistently held that neither the PSLRA safe harbor, nor the bespeaks-caution doctrine protects material omissions." *Wilson v. LSB Indus., Inc.*, No. 15 Civ. 7614, 2017 WL 7052046, at *3 (S.D.N.Y. Mar. 2, 2017); *accord Rudani v. Ideanomics, Inc.*, No. 19 Civ. 6741, 2020 WL 5770356, at *6 (S.D.N.Y. Sept. 25, 2020); *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 304 (S.D.N.Y. 2018). Defendants argue that their alleged misstatements are protected by the first and third prongs.

Defendants argue that statements regarding Axsome's suppliers are forward-looking statements accompanied by meaningful cautionary language. However, even if the challenged statements qualify as forward-looking, they are actionable because "[c]autionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired." *Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004); *accord Ray v. StoneCo Ltd.*, No. 21 Civ. 9620, 2024 WL 4308130, at *10 (S.D.N.Y. Sept. 25, 2024). For example, Defendants rely on the following language in Axsome's 2021 and 2022 public filings: "If the manufacturers upon whom we rely fail to produce our product candidates in the volumes that we require on a timely basis . . . we may face delays in the development and commercialization of . . . our products and may lose potential revenues." However, as discussed above, the SAC sufficiently alleges that, when those statements were made, "manufacturers upon whom [Defendants] rel[ied]" were already facing supply issues that were delaying "the development and commercialization" of AXS-07.

Defendants similarly argue that "statements regarding the promise of Axsome's AXS-07 NDA based on its clinical trial results are not actionable" because they are forward-looking statements accompanied by meaningful cautionary language. First, Defendants mischaracterize

Plaintiffs' challenge to Defendants' statements about AXS-07's NDA submission. The SAC does not allege that Defendants "promise[d]" FDA approval, but instead that Defendants "promote[d] the likely approval of AXS-07" while being aware of facts that materially decreased the likelihood of such approval. Second, Defendants' cautionary language regarding AXS-07's NDA submission is insufficient because the disclosed risks had already transpired. For example, Defendants rely on language in the Company's 2021 public filings warning that "[d]ata obtained from clinical trials are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data." But the SAC adequately alleges that Axsome could not obtain sufficient "[d]ata . . . from clinical trials" to include in AXS-07's NDA due to supplier delays. Thus, there was inadequate data regarding AXS-07's NDA for the FDA to "interpret." Because the disclosed potential risks had materialized, the first prong of the PSLRA's Safe Harbor, or the related bespeaks doctrine, do not apply. *See Behrendsen v. Yangtze River Port & Logistics Ltd.*, No. 19 Civ. 00024, 2021 WL 2646353, at *7 (E.D.N.Y. June 28, 2021) (cautionary words insufficient where, "at the time they were made . . . the disclosed potential risk had materialized").

As to the third prong of actual knowledge that the forward-looking statements were false or misleading, Defendants cannot avail themselves of the PSLRA's Safe Harbor because it does not protect material omissions such as those alleged in the SAC. *See Rudani*, 2020 WL 5770356, at *6 (holding that defendants' forward-looking statements were not protected by the PSLRA's safe harbor at the motion to dismiss stage because "[p]laintiff allege[d] that [d]efendants omitted material information"). The PSLRA's Safe Harbor also does not protect the alleged misstatements regarding AXS-07's NDA and Axsome's manufacturing capabilities because, as discussed below regarding scienter, the SAC sufficiently alleges the "actual

knowledge" prong. The SAC raises a strong inference, at least as compelling as any opposing inference, that Defendants knew about undisclosed manufacturing problems and supply delays that would seriously undermine Axsome's ability to obtain AXS-07's NDA approval. *See Slayton v. Am. Exp. Co.*, 604 F.3d 758, 775 (2d Cir. 2010) (actual knowledge precludes the safe harbor if "a reasonable person would . . . deem an inference that the defendants . . . were aware of undisclosed facts tending to seriously undermine the accuracy of the statement, cogent and at least as compelling as any opposing inference"); *accord In re Mindbody, Inc. Sec. Litig.*, 489 F. Supp. 3d 188, 203 (S.D.N.Y. 2020).

Statements of opinion. Second, Defendants argue that the SAC's alleged misstatements are inactionable because they were statements of opinion. Statements of opinion may be actionable misstatements if (1) "the speaker did not hold the belief she professed," (2) "the supporting fact[s] she supplied were untrue" or (3) the stated opinion "omits material facts about the [speaker's] inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 186, 189 (2015); *see Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (applying *Omnicare* beyond Section 11 claims to Section 10(b) and Rule 10b-5 claims); *accord Ray*, 2024 WL 4308130, at *6 (same).

As discussed above, regardless of the sincerity of Defendants' beliefs, the SAC sufficiently alleges that Defendants omitted material facts regarding the challenged opinion statements, such as when they stated in public filings that they "believe[d] [their] existing suppliers" related to AXS-07 would "be capable of providing sufficient quantities . . . to meet our clinical trial supply needs," when at the same time their suppliers were unable to provide

sufficient quantities even for stability studies for the NDA. The SAC adequately pleads that the challenged opinion statements were misleading.[2]

Defendants' argument that Plaintiffs have "cherry-picked snippets of Defendants' actual statements" by omitting Defendants' "expression[s] of belief" is without merit. Even evaluated in the context of the word "belief," the opinion statements are actionable because the SAC alleges that the challenged statements omitted the "material fact" that Defendants were unable to conduct studies due to manufacturing delays, which "conflict[s] with what a reasonable investor would take" from Defendants' opinion statements. *Tongue*, 816 F.3d at 210.

Puffery. Third, Defendants argue that some of the challenged statements are inactionable because they were mere puffery, such as their statements that "2021 was a year of continued progress which has put [Axsome] in a position to potentially launch" AXS-07. "Puffery encompasses statements that are too general to cause a reasonable investor to rely upon them, and thus cannot have misled a reasonable investor." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d at 245. However, statements are not puffery where they constitute "misrepresentations of existing facts" and the speaker "knew the contrary was true." *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000); *accord Nutriband, Inc. v. Kalmar*, No. 19 Civ. 2511, 2020 WL 4059657, at *9 (E.D.N.Y. July 20, 2020). Here, none of the statements identified by Defendants qualify as puffery. The SAC sufficiently alleges that Defendant Tabuteau's statement that "2021 was a year of continued progress which has put [Axsome] in a position to potentially launch" AXS-07

[2] Defendants raise arguments regarding additional opinion statements challenged by Plaintiffs in a footnote. This Order and Opinion addresses only Defendants' arguments regarding Plaintiffs' challenged opinion statements raised in the text of Defendants' memorandum of law. *See United States v. Restrepo*, 986 F.2d 1462, 1463 (2d Cir. 1993) ("We do not consider an argument mentioned only in a footnote to be adequately raised or preserved for appellate review."); *accord City of Philadelphia v. Bank of Am. Corp.*, 498 F. Supp. 3d 516, 537 (S.D.N.Y. 2020).

misrepresented material facts in light of Axsome's manufacturing and supply problems which prevented it from conducting necessary studies for the NDA.

Not so incomplete as to mislead and Defendants' duty to disclose. Fourth, Defendants argue that several challenged statements are accurate statements of fact that were not so incomplete as to mislead, such as their statements describing AXS-07's manufacturing process, AXS-07's testing results and the ICH guidelines that governed stability testing. Defendants further argue that they did not have a duty to disclose any negative interim FDA feedback they may have received regarding their manufacturing facilities. Both of these arguments fail because, as discussed above, the SAC sufficiently alleges that Defendants failed to disclose that Axsome's vendor was experiencing equipment problems that were causing an insufficient supply of AXS-07 when describing the Company's manufacturing capabilities. The SAC also adequately pleads that those equipment problems impacted the likelihood of NDA approval because they were delaying AXS-07's stability testing timeline, which could not be "sped up" under the ICH guidelines. Such information was material and "necessary to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Moreover, even if Defendants are correct that they did not have a duty to disclose interim FDA feedback, the SAC still sufficiently alleges other facts with particularity (such as information provided by CW 1) to support the inference that Axsome was experiencing manufacturing and supplier issues that Defendants were obligated to disclose to make other statements not misleading.

Defendants' argument that, "even if it were true that Axsome was unable to manufacture AXS-07 at some point during the NDA process," such information would "not [be] inconsistent with Axsome's statements" is unconvincing. As discussed above, the SAC sufficiently alleges

that Axsome's inability to manufacture AXS-07 was inconsistent with its statements regarding AXS-07's NDA application and manufacturing, such as Axsome's statement that it "belie[ved their] existing suppliers" related to AXS-07 would "be capable of providing sufficient quantities . . . to meet our clinical trial supply needs."

2. Scienter

The SAC sufficiently pleads scienter as to Defendants Tabuteau, Jacobson and Axsome. The SAC fails to allege scienter as to Defendants O'Gorman and Pizzie. The PSLRA requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "For an inference of scienter to be strong, as required by the PSLRA, a reasonable person must deem it cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Set Cap. LLC*, 996 F.3d at 78. "In making this determination, the court must review all the allegations holistically." *Matrixx Initiatives, Inc.*, 563 U.S. at 48.

A plaintiff may satisfy the scienter requirement by "alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 212 (2d Cir. 2020). "Circumstantial evidence can support an inference of scienter in a variety of ways, including where defendants . . . knew facts or had access to information suggesting that their public statements were not accurate" or "failed to check information [that it] had a duty to monitor." *Blanford*, 794 F.3d at 306; *accord Denny v. Canaan Inc.*, No. 21 Civ. 3299, 2023 WL 2647855, at *12 (S.D.N.Y. Mar. 27, 2023). "[W]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Teamsters Loc. 445 Freight Div. Pension Fund v.*

Dynex Cap. Inc., 531 F.3d 190, 196 (2d Cir. 2008). "To prove liability against a corporation, . . . a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation." *Id.* at 195.

a. Defendants Tabuteau, Jacobson and Axsome

As to Defendants Tabuteau, Jacobson and Axsome, the SAC's allegations, if proven, would constitute strong circumstantial evidence of recklessness and are sufficient to support an inference of scienter that is "at least as compelling as any opposing inference one could draw from the facts alleged." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). The SAC alleges that Axsome is a small pharmaceutical company with only about 100 full-time employees as of early 2022. The Company has a limited CNS portfolio, of which AXS-07 was a core product, and the one closest to commercialization. The Individual Defendants' public statements evinced a strong familiarity with AXS-07's manufacturing process. For example, Defendant Tabuteau, Axsome's CEO and founder, stated that he was "involve[d] in almost every aspect associated with the development, implementation, and realization of . . . drug development products." He responded to an analyst question about a delay of the NDA submission explaining "we are waiting on one vendor report . . . ." and confirmed that the same manufacturer produced both the trial and commercial batches of AXS-07. On another occasion, he explained to an analyst that gathering additional stability studies "is standard information when you manufacture additional batches." Defendant Jacobson regularly spoke to analysts and investors regarding the manufacturing of AXS-07. For example, on a November 5, 2020, earnings call, Defendant Jacobson explained to an analyst how Axsome

planned to use additional manufacturing information to "make [AXS-07's NDA] package as robust as possible."

The SAC alleges that Defendants Tabuteau and Jacobson had access to specific information that contradicted their public statements. The SAC describes how, in a July 2021 FDA report regarding an inspection of one of Axsome's facilities related to AXS-05, Defendant Tabuteau "identified himself as the most responsible person" for the Company, stated that he "has oversight over . . . five key product development departments" such as the quality assurance, operations and clinical development departments, and is "involve[d] in almost every aspect associated with the development, implementation, and realization of . . . drug development projects." On an earnings call, Defendant Tabuteau also referenced a specific report from one of Axsome's manufacturing vendors.

While Defendants argue that those statements alone are insufficient to allege that Defendant Tabuteau had access to information contradicting his public statements, Plaintiffs rely on more than just Tabuteau's position and self-described responsibilities to support an inference that he had access to such information. For example, as discussed above, Defendant Tabuteau's public statements evinced familiarity with AXS-07's NDA submission and manufacturing. Taken together, the SAC's allegations support an inference that Defendant Tabuteau, the CEO of a small pharmaceutical company who was involved in "almost every aspect" of the Company's drug development projects, had access to the alleged information that contradicted his public statements.

The SAC adequately alleges that Defendant Jacobson had access to specific information contradicting his public statements. CW 1 stated that Defendant Jacobson supervised Liu, who provided him with updates about AXS-07's supply issues. The scienter of Jacobson and

Tabuteau is imputed to Axsome because, as COO and CEO, respectively, they were agents of the Company whose scienter is imputed to the Company. *See Jackson v. Abernathy*, 960 F.3d 94, 98-99 (2d Cir. 2020).

Defendants' arguments disputing scienter are unavailing. Defendants first argue that the SAC's allegations about CW 1's information are insufficient to "support any inference of scienter" because it does not allege that CW 1 had direct contact with any Individual Defendant, offer specifics about the alleged equipment problems Axsome was facing or include allegations to "support [the assumption] that Axsome was unable to manufacture [AXS-07] for the entire Class Period." However, CW 1's information need not be based on direct contact with the Individual Defendants to be reliable. CW 1 detailed the information made available to her by Liu, Axsome's Senior Director of AXS-07's Supply Chain, including AXS-07's supply issues. CW 1 also experienced firsthand the supply delays that postponed the study that CW 1 was supposed to oversee. CW 1 also described how Defendant Jacobson had access to information contradicting his public statements through reports from Liu.

Similarly, CW 1 provided sufficient information about Axsome's equipment issues. CW 1 described how Axsome used three vendors to create AXS-07, and how the third vendor who ultimately created the drug was "having problems with the equipment used to combine the two ingredients." CW 1 further stated that "the whole supply of AXS-07 for trial and commercial uses was manufactured at the same facility," which "delayed Axsome's entire supply of AXS-07, not just batches that were intended for use in trials." While CW 1 may not have worked at that vendor's manufacturing facility, the SAC plausibly alleges that, by virtue of CW 1's position and responsibilities as a Senior Clinical Trial Manager at Axsome, CW 1 was in a position to "possess the information alleged" about the vendor's manufacturing difficulties in producing a

sufficient quantity of Axsome's AXS-07 to conduct studies for submission with the NDA. *See Blanford*, 794 F.3d at 305. CW 1's allegations, taken together with other allegations that the Individual Defendants were executives at a small company about to seek FDA approval for a key product, were involved in or familiar with the development of Axsome's products, and were the spokespersons who informed the public about a key product and its manufacturing, supports an inference of scienter at least as compelling as any opposing one. *See Oklahoma Firefighters Pension & Ret. Sys. v. Lexmark Int'l, Inc.*, 367 F. Supp. 3d 16, 37 (S.D.N.Y. 2019) (allegations regarding the importance of a defendant's key product to its business, "[w]hile not dispositive," can "move[] the needle in plaintiffs' favor" and support an inference of scienter).

Defendants further argue that Plaintiffs cannot rely on post-Class Period statements to support inferences about any Defendant's state of mind during the Class Period. The SAC relies on several post-Class Period statements. In a September 2022 press release, Axsome stated that it held a meeting with the FDA "to obtain the FDA's feedback and agreement on the Company's plan to address the issues raised" by the FDA and that "based on the FDA feedback, the Company will include new [CMC] information." On a November 2022 earnings conference call, Defendant Jacobson stated that the "stability data" the FDA requested on new batches of AXS-07 would require "various stability protocols" that can "typical[ly]" run for over twelve months and "cannot be sped up." These post-Class Period statements point to Defendants knowledge of typical stability testing requirements for AXS-07 during the Class Period. The statements also provide additional support for the SAC's theory of Defendants' conscious misbehavior and reckless disregard because they illustrate that Defendants knew that AXS-07's June 2021 NDA would likely be deficient due to supply delays that limited stability testing -- which Defendants were aware typically required a year to fulfill -- in early 2021. *See In re Avon Sec. Litig.*, No. 19

Civ. 01420, 2019 WL 6115349, at *20 (S.D.N.Y. Nov. 18, 2019) ("The Second Circuit has repeatedly held that district courts may draw inferences favorable to the Plaintiff in a PSLRA case from post-Class Period events and statements.").

Finally, Defendants argue that the SAC insufficiently pleads scienter because it improperly relies upon allegations regarding issues with AXS-05 and Defendants' use of the word "unresolved" when describing issues the FDA identified regarding AXS-07's NDA in Axsome's April 2022 press release. However, these are not the SAC's principal allegations. Even absent consideration of such allegations, as discussed above, the SAC's many other allegations of scienter taken together sufficiently support an inference of conscious misbehavior or recklessness at least as compelling as any opposing one provided by Defendants.

b. Individual Defendants Pizzie and O'Gorman.

The SAC fails to allege scienter as to Defendants Pizzie and O'Gorman. The SAC relies almost entirely on Pizzie and O'Gorman's positions as Axsome's CFO and Senior Vice President of Clinical Development and Medical Affairs, respectively, to support an inference that they must have known about the undisclosed manufacturing issues. However, the SAC does not allege facts that either Defendant had access to information regarding the manufacturing issues, or even that anyone familiar with AXS-07's manufacturing reported to either Defendant. The SAC alleges that Defendant Pizzie's scienter is established by his Sarbanes-Oxley ("SOX") certification signings, in which he certified that Axsome's public filings "do[] not contain any untrue statement of material fact or omit to state a material fact." "However, a plaintiff cannot raise an inference of fraudulent intent based on the signing of a [SOX] certification without alleging any facts to show a concomitant awareness of or recklessness to the materially misleading nature of the statements." *Francisco v. Abengoa, S.A.*, 559 F. Supp. 3d 286, 321

(S.D.N.Y. 2021); *see Venkataraman v. Kandi Techs. Grp., Inc*., No. 20 Civ. 8082, 2021 WL 4952260, at *4 (S.D.N.Y. Oct. 25, 2021) ("[C]ourts in this circuit regularly hold that the signing of a SOX certification, without more, is insufficient to plead scienter.").

3. Loss Causation

The SAC sufficiently pleads loss causation. "Loss causation . . . is the proximate causal link between the alleged misconduct and the plaintiff's economic harm." *ATSI Commc'ns, Inc.* 493 F.3d at 106; *accord In re Omega Healthcare Invs., Inc. Sec. Litig.*, 563 F. Supp. 3d 259, 265 (S.D.N.Y. 2021). To plead loss causation, a complaint must allege "that the subject of the fraudulent statement or omission was the cause of the actual loss suffered." *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 179 (2d Cir. 2020); *see Lea v. TAL Educ. Grp.*, 837 F. App'x 20, 27 (2d Cir. 2020) (summary order) (holding that loss causation requires the complaint to plead "that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement"). "Generally, plaintiffs sufficiently plead loss causation when they allege that their share's price fell significantly after the truth became known through an express, corrective disclosure or through events constructively disclosing the fraud like the materialization of the risk concealed." *Abramson*, 965 F.3d at 179.

The SAC sufficiently pleads loss causation. The fraud claim is based on the allegation that Axsome experienced significant problems in the manufacturing process for its new drug, AXS-07, and what these problems presaged for the timing and prospect of FDA approval. The alleged fraudulent conduct is Defendants' failure to disclose these manufacturing problems, and Defendants' resulting misleading statements about the prospect of FDA approval. The SAC alleges that the concealed information was disclosed to the market in Axsome's April 25, 2022,

press release, causing Axsome's stock price to drop approximately 22% that day. These allegations are sufficient to plead loss causation.

Defendants' arguments to the contrary are unavailing. Defendants argue that the SAC "fail[s] sufficiently to allege that the basis for the FDA's denial of the NDA was Axsome's inability to manufacture AXS-07" because the FDA stated only that "CMC issues" -- which can encompass not only manufacturing but also many unrelated areas -- were "unresolved." Defendants also argue that the April 2022 disclosure did not reveal new information because it was the materialization of a known risk -- "that the FDA may reject its NDA for any number of reasons." As discussed above, the SAC's allegations give rise to the reasonable inference that the CMC issues to which the FDA referred were the manufacturing issues described throughout the SAC. Defendants can test that inference at a later stage of litigation. As to disclosure of a known risk of FDA rejection, the SAC alleges that undisclosed manufacturing issues created a particular risk that the FDA would reject the AXS-07 NDA. The SAC adequately pleads loss causation.

C. Section 20(a) Violation

Section 20(a) imposes joint and several liability on control persons for underlying violations of the Exchange Act. *See* 15 U.S.C. § 78t. To state a claim under § 20(a), a plaintiff must allege both a primary violation of the Exchange Act and control over the primary violator. *See Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014); *accord Li v. Eqonex Ltd.*, No. 23 Civ. 03346, 2024 WL 4241951, at *16 (S.D.N.Y. Sept. 18, 2024). Because the primary claim fails as to Individual Defendants Laliberte, Pizzie and O'Gorman, the § 20(a) claim is dismissed as to them as well. While Plaintiffs urge the Court to "re-evaluate" the pleading standard for § 20(a), the Court declines to do so. *See Steamfitters'*

Indus. Pension Fund v. Endo Int'l PLC, 771 F. App'x 494, 498 (2d Cir. 2019) ("To state a claim for so-called 'control person liability' under Section 20(a), a plaintiff is required to establish, among other things, 'a primary violation' of the securities laws."); *accord High Income Sec. Fund v. Cedar Realty Tr., Inc.*, No. 22 Civ. 4031, 2023 WL 6214237, at *10 (E.D.N.Y. Sept. 25, 2023).

As to Defendants Tabuteau and Jacobson, Defendants main argument for dismissal of this claim is that, if the primary claim fails, so too must the secondary liability claim. As the Court has denied Defendants' motion to dismiss Plaintiffs' § 10(b) claim, and Plaintiffs have otherwise adequately alleged a control person violation, the motion to dismiss Plaintiffs' § 20(a) claim as to Defendants Tabuteau and Jacobson is denied.

IV. CONCLUSION

For the foregoing reasons, the motion to dismiss of Defendants' Axsome, Tabuteau and Jacobson is **DENIED**. Defendants' Laliberte, O'Gorman and Pizzie's motion to dismiss is **GRANTED**. Plaintiffs' request for oral argument is **DENIED** as moot.

The Clerk of Court is respectfully directed to close the motion at Dkt. Nos. 79 and 82.

Dated: March 31, 2025
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE